

**REMARKS**

Introductory Comments:

Claims 28-45 were examined in the Office Action under reply and rejected under (1) 35 U.S.C. §112 second paragraph; (2) 35 U.S.C. §102(b); and (3) 35 U.S.C. §102(e). Additionally, claims 28-35 and 40-45 were rejected under the judicially created doctrine of obviousness-type double patenting. These rejections are respectfully traversed as discussed more fully below.

Overview of the Above Amendments:

The specification has been amended to correct an obvious typographical error. In particular, the amended paragraphs now clarify that microliter volumes are added to the test strip. A review of the specification as a whole evidences that microliters were indeed intended. In particular, all of the examples use microliter volumes. Moreover, one of skill in the art would readily know that liter volumes of reagents would not be added to a test strip. Accordingly, entry of this amendment is respectfully requested.

Claims 1-27, 32-35, 40, 41 and 46-63 have been cancelled. Claims 28-31, 36-39 and 43-45 have been amended in order to recite the subject invention with greater particularity. Specifically, claims 28, 29 and 45 have been amended to clarify the relative positions of the various components of the test strip, as requested by the Office. Claims, 29-31 and 44-45 have been amended to recite that the method comprises additional steps. Claims 36-39 have been amended to correct an obvious typographical error as pointed out by the Office.

Support for the foregoing amendments can be found throughout the specification at, e.g., page 2, lines 12-29; page 4, lines 19-26; page 5, lines 18-29; pages 34-35, bridging paragraph; in the examples and in the figures.

Cancellation of claims 1-27, 32-35, 40, 41 and 46-63 and amendment of claims 28-31, 36-39 and 43-45 is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly

reserve the right to file one or more continuing applications hereof containing the canceled or unamended claims.

Rejections Under 35 U.S.C. §112, Second Paragraph:

Claims 28-35 were rejected under 35 U.S.C. §112, second paragraph as indefinite. In particular, the Office asserts the claims “are vague and indefinite with respect to the placement of the different zones on the test strip.” Office Action, page 2. Additionally, claims 29-35 and 43-45 were rejected as indefinite “because they appear to be limitation of a device and not a method.” Office Action, page 3. Claims 36-39 were rejected as indefinite based on the recitation of liter quantities of buffer. The rejections of claims 32-35, 40 and 41 are moot due to cancellation of these claims.

As explained above, the claims have been amended to clarify the relative positions of the different zones on the test strip. Moreover, the term “ $\mu$ L” has been substituted for “L” in claims 36-39. Finally, claims 29-35 and 43-45 have been amended to clarify that the method comprises additional steps.

Accordingly, these bases for rejection have been overcome and withdrawal thereof is respectfully requested.

Rejections Under 35 U.S.C. §102:

Claims 28-45 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,726,010 to Clark (“Clark”). The Office alleges Clark discloses “a reversible flow chromatographic binding assay device and method” as claimed in the present application. However, applicants submit that Clark fails to anticipate the present claims.

The law is clear that in order to anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986). *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements “arranged as in the claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 722 F.2d

1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clar Corp.* 713 F.2d 760, 771, 218 USPQ 2d 781, 789 (Fed. Cir. 1983, cert. denied, 465 U.S. 1026 (1984)). Clark does not describe a method as claimed and therefore cannot anticipate the present claims.

In particular, all of the present claims specify that buffer is delivered to “prewet” the test strip. Clark, on the other hand, does not prewet the strip with buffer. As explained throughout Clark, sample is first applied to the device and allowed to flow through the device to saturate the flow matrix. See, for example, column 6, lines 35-37. As explained in the present specification, prewetting provides several advantages. In particular, prewetting minimizes flow rate differences and allows sample to flow within the test strip at a more consistent velocity, thereby yielding more accurate and precise results. See, page 3, lines 19-23; page 11, lines 12-18; and page 13, lines 3-7. Thus, Clark fails to anticipate the claims and withdrawal of this basis for rejection is respectfully requested.

Claims 28-45 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,528,323 to Thayer et al. (“Thayer”). The Office correctly notes that Thayer has a common inventor with the present application and that this reference can be overcome by eliminating Thayer by means of a Declaration pursuant to 37 CFR §1.132. Applicants are providing a Declaration of Inventorship that satisfies the requirements of MPEP §706.02(k)(C). Thus, the Thayer patent is not “an application for patent by another” and is therefore not properly citable art against the present application. Withdrawal of this basis for rejection is therefore respectfully requested.

The Double Patenting Rejection:


Claims 28-35 and 40-45 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-41 of Thayer. Applicants are submitting a Terminal Disclaimer in compliance with 37 CFR §1.321(c). Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

**CONCLUSION**

Applicants respectfully submit that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested: If the Examiner notes any further matters which he believes may be resolved by a telephone interview, he is encouraged to contact the undersigned by telephone at 650-493-3400.

Respectfully submitted,

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